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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,394	02/24/2004	Steve A. Yon	137001	6524

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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/785,394

Applicant(s)

YON, STEVE A.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-17 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 and 32 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-17 and 20-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### ***Entry of Amendment***

Applicant's amendment filed on October 8, 2006 is acknowledged. Claims 4 and 19 have been canceled by the Applicant, therefore, claims 1-3, 5-18 and 20-32 are currently pending.

### ***Prior Rejections or Objections***

The following comments pertain to the rejections or objections in the most recent Office action mailed on 5/8/2006. Rejections under 35 U.S.C. 102 and 103 are maintained because of a new reading of the Dobak reference as presented below. Therefore, this Office action is non-final.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the multiple outlet lumens of claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-16, 18 and 20-30 rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (6,261,312). Dobak et al. disclose a catheter system and its method of use in changing the temperature of the blood by heat transfer to and from a circulating working fluid, comprising the identical structure as claimed by Applicant (Figure 3 of Dobak), wherein the heat transfer element is a balloon made of rubber with flexible supply and return lumens capable of undergoing inflation, wherein the working fluid is saline, wherein the length of the supply lumen is between 5 and 30 cm, wherein the helical shape of the return lumen is less than about 8 mm when inflated, wherein the

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working fluid supply is configured to produce a pressurized working fluid at a temperature of between about -3 to 36°C and at a pressure below about 5 atm, and wherein the return lumen includes a surface coating including heparin (col. 3, lines 7-19 and line 45-col. 4, line 28, col. 8, lines 35-46, col. 9, lines 32-58 col. 15, lines 57-61 and col. 16, lines 1-36).

Amended claim 1 now recites "wherein multiple helical return lumens are provided". But, Dobak et al. disclose in col. 10, lines 38-42: "that a separate embodiment may also be constructed in which the inlet lumens each provide working fluid to their corresponding outlet lumens". This is a modification of Figure 3 of Dobak et al. and is the exact sentence of the Applicants specification (0149). This was overlooked by the examiner because the Applicants Figure 21 is exactly the same as Dobak's Figure 3 and the figures only show a single outlet or return lumen. Figure 3 of Doback also show three outlet lumens corresponding to the three inlet lumens (claims 5 and 20 limitation).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak et al. in view of Dato (3,325,419). Dobak et al. fail to disclose the heat transfer element is made of a flexible conductive metal. But, Date discloses a catheter for heat

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exchange with the blood in the vasculature and which is made of stainless steel, suggesting that it would have been obvious to a skillful artisan to modify the device of Dobak et al. as disclosed by Dato, to provide a catheter with higher thermal conductivity and therefore, higher heat transfer for the application (see Dato, col. 3, lines 3-60).

***Allowable Subject Matter***

Claims 31-32 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Roy D. Gibson  
Primary Examiner  
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October 25, 2006